

REMARKS

Claims 56-58, 61-65, 67-76, and 78-81 are pending in the application. Claims 56, 71 and 78 are independent.

The Examiners notes in the main body of the office action that “(t)his Office Action is in response to the Amendment filed February 4, 2008. All previous rejections have been withdrawn unless stated below.... This action is made NON-FINAL.”

Therefore, even though the “Final” box is checked on page 2 of the Office Action, Applicant is assuming that this is a non-final office action as stated in the quote above.

Reconsideration and favorable action are respectfully requested.

Response

Claim Rejections - 35 USC § 103 - Obviousness (New Rejection)

1) Claims 56-58, 61, 63, 64, 67-73, 75, 76, 78, 80 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (US 5,085,853) in view of Horner et al. (US 5,829,639).

Williams et al. disclose two part oral compositions wherein one part comprises peroxide or a peroxide releasing component and the second part comprises bicarbonate. The compositions are formulated into gels and pastes may be kept isolated in a separate compartment of a dispenser such as those disclosed by Schaeffer (US 4,849,213), which shows a dispenser comprising a compartment where the two components mix before being dispensed from the dispenser (Fig. 1 of Schaeffer). The mixture of the two components will provide a composition with a pH ranging from 7.0 to 9.5 (col. 4, lines 3-9). The peroxide releasing component includes an alkali metal percarbonate. The compositions may also comprise tartar control agents such as

disodium pyrophosphate (col. 4, lines 47-58). Humectants include polyethylene glycol and may comprise 25 to 90% by weight and water may comprise 3 to 30% by weight. The reference differs from the instant claims insofar as it does not disclose the dispensers comprise a static mixer, the peroxide component is an anhydrous gel as in claim 71 and the compositions comprise 70% water as in claim 61.

Horner et al. disclose dispensers for flowable materials such as toothpastes. The dispensers comprise static mixers having baffles. The ingredients are mixed during passage through the discharge nozzle prior to discharge (col. 5, lines 8-12). The dispenser is a single piece, inexpensive disposable package for storing and dispensing flowable materials. It has at least two isolated chambers connected to a discharge nozzle so that the contents of the chambers are isolated until discharge. It is reliable, comfortable to hold and easy to use and comprises a static mixer for intermixing the contents of the cylinders prior to discharge. The dispenser also has a maintained dispensing volumetric ratio where the pistons travel is non-linear (col. 1, lines 53-67). The reference differs from the instant claims insofar as it does not disclose the types of toothpaste or its components that may be dispensed from the dispensers. It would have been obvious to one of ordinary skill in the art to have used the dispenser comprising the static mixer to dispense the compositions of the primary reference motivated by the desire to use a dispenser that is inexpensive disposable, has at least two isolated chambers connected to a discharge nozzle so that the contents of the chambers are isolated until discharge, is reliable, comfortable to hold and easy to use and comprises a static mixer for intermixing the contents of the cylinders prior to discharge, as disclosed by the secondary reference.

In regards to the amount of water in the compositions, normally, changes in result effective variables are not patentable where the difference involved is one of

degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. See MPEP 2144.05, II. It would be obvious to one of ordinary skill in the art to have adjusted the amount of water to at least 70% water by weight motivated by the desire obtain a compositions with optimal efficacy.

In regards to the peroxide component being anhydrous, percarbonates react with water to form hydrogen peroxide. Omission of an element and its function is obvious if the function of the element is not desired. See MPEP 2144.04, II. It would have been obvious to one of ordinary skill in the art to have removed water from the compositions when using percarbonates or made anhydrous compositions when using percarbonate motivated by the desire to inhibit the formation of hydrogen peroxide prematurely and ensuring a stabilized composition.

Applicant respectfully traverses the rejection.

The reference Schaeffer (US 4,849,213) has been fully addressed in previous office action responses.

As noted before, Schaeffer discloses a 2-component tooth paste or dentifrice in "a combination of a collapsible tube article having flexible side walls and a composition consisting of a gel component and a paste component and contained in said article, said combination being suitable for use in combating gum disease," with the first compartment containing a gel having "(i) 1-10% by volume of hydrogen peroxide, (ii) 0.05-1.2% by volume of a water dispersible copolymer of acrylic acid cross-linked with polyallyl sucrose; (iii) 0.1-1.5% by volume of a non-ionic cellulose gum stabilizer (iv) purified water and (iv) a neutralizing agent selected from the group consisting of sodium hydroxide, potassium hydroxide, triethanolamine, diisopropylamine and ammonia in an amount sufficient to raise the pH of said gel to within about 3-6 said first

compartment having an orifice for dispensing controlled amounts of said gel upon squeezing of said flexible sidewalls;” and a second compartment containing a paste having “(i) 10-50% by weight of sodium bicarbonate; (ii) 1-6% by weight of a salt selected from the group consisting of NaCl and MgSO.sub.4 ; (iii) 1-3% by weight of a thickener-stabilizer selected from the group consisting of cellulose gum magnesium aluminum silicate, and mixtures thereof; (iv) 5-30% by weight of a humectant selected from the group consisting of glycerin, sorbitol, polyethylene glycol and polypropylene glycol, (v) purified water and (vi) 1-40% by weight of a cleaning-polishing agent selected from the group consisting of CaSO.sub.4, Ca.sub.3 (PO.sub.4).sub.2 and hydrated aluminum oxide, and (viii) 0.1-2.5% by weight of sodium lauryl sulfate.” See abstract. (Emphasis added) Thus, claims 56, 71 and 78 are patentable over Schaeffer.

Also, Williams et al. (5,085,853) disclose an oral composition “having a first peroxide-containing component and a second bicarbonate-containing component. The first component has a flavor which is reactively incompatible with bicarbonate salts while the second component has a flavor which is reactively compatible with the bicarbonate.” See Abstract. The “oral composition comprising:

(A) a first component comprising:

(i) a peroxygen compound present in an amount from about 0.1 to about 10% by weight of the first component;

(ii) a first flavor agent which is reactively incompatible with bicarbonate salts, the first flavor agent being present in an effective amount to impart a flavor taste;

(B) a second component comprising:

(i) a bicarbonate salt present in an amount from about 0.5 to about 80% by weight of the second component;

(ii) a second flavor agent which is reactively compatible with the bicarbonate salt, the

second flavor agent being present in an effective amount to impart a flavor taste, the components being held in separate areas of a container for the oral composition, and relative weight amounts of the first and second components ranging from about 2:1 to 1:20.

Methyl salicylate is the preferred first flavor agent. Menthol may be formulated with the bicarbonate component as the second flavor agent. Advantageously, the relative weight ratio of the first to second flavor agent should range from about 1:1 to about 1:15, with a ratio of about 1:2 being optimum. "See Col. 2, lines 14-41. (Emphasis added)

"A low pH, preferably a pH no higher than about 3, optimally less than 3.0, should be maintained for the gel component. Acidification is best accomplished through use of a phosphorus-based inorganic or organic acid." See Col. 3, lines 63-66. (Emphasis added)

Williams et al are concerned with finding a flavor that is compatible with sodium bicarbonate in the same component with sodium bicarbonate, as sodium bicarbonate is a major ingredient of the second component, up to about 80% by weight, and a flavor that is not compatible with sodium bicarbonate in a separate component. The first component also has a low pH of no higher than 3.

Thus, in addition to not disclosing the dispensers comprising a static mixer, or that the peroxide component is an anhydrous gel as in claim 71, and that the compositions comprise 70% water as in claim 61, as admitted by the Examiner, Williams et al do not disclose a stabilizing agent or a chelating agent.

In addition, as noted above, Williams et al. also disclose "(a) low pH, preferably a pH no higher than about 3, optimally less than 3.0, should be maintained for the gel

component. Acidification is best accomplished through use of a phosphorus-based inorganic or organic acid.” See Col. 3, lines 63-66. (Emphasis added)

Horner (5,829,639) et al. disclose “an inexpensive single piece molded dispenser with multiple chambers for the isolated storage and dispensation of desired amounts of flowable materials wherein the single piece molded dispenser comprises a driving member, a storage member with multiple storage chambers where the storage chambers can have any shape, however, round chambers offer the lowest cost to produce and a hinged member with two living hinges (repeatedly foldable plastic members integral with the elements they interconnect).” See Col. 2, lines 17-26.

Applicant would like to point out that the present invention was filed on November 1, 2001, and “is a continuation of U.S. Patent Application No. 09/054,156, filed April 12, 1998, now U.S. Patent No. 6,312,670; which in turn is a divisional of U.S. Patent Application No. 08/719,569, filed September 25, 1996, now U.S. Patent No. 5,922,307; which claims priority from U.S. Provisional Application No. 60/004,258, filed September 25, 1995; each of which are incorporated herein by reference.” See priority claim for the present application. Horner et al. have a filing date of October 31, 1996. Thus, the priority date of the present application is prior to that of the Horner et al. patent. Thus, given the respective dates based on the information available to the Applicant, Horner et al. cannot constitute a proper citation for the rejection and the rejection is moot, unless the Examiner is aware of other data that is not immediately apparent to the Applicant.

Three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior

art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142.

Applicant respectfully submits that since the Horner et al. reference is not a proper reference against the present invention, the deficiencies of Williams et al. noted above are not supplied. Therefore, claims 56, 71 and 78 are patentable.

Claims 57-58, 61, 63, 64, 67-70, 72-3, 75, 76, 80 and 81 are dependent from claims 56, 71 and 78, respectively, and are also rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (US 5,085,853) in view of Horner et al. (US 5,829,639). While Applicant does not acquiesce with the particular rejections to dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claims 56, 71, and 78. These dependent claims include all of the limitations of the base claims and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 57-58, 61, 63, 64, 67-70, 72-3, 75, 76, 80 and 81 are also in condition for allowance.

Applicant respectfully requests that the rejection of claims 56-58, 61, 63, 64, 67-73, 75, 76, 78, 80 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (US 5,085,853) in view of Horner et al. (US 5,829,639) be withdrawn. Reconsideration is respectfully requested.

2) Claims 62, 75 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (US 5,085,853) in view of Horner et al. (US 5,829,639) as applied to claims 56-58, 61, 63, 64, 67-73, 75, 76, 78, 80 and 81 in further view of Burke et al. (US 5,292,502).

The primary and secondary references, Williams et al. and Horner et al. are discussed above. Williams et al. disclose sodium bicarbonate should be incorporated

into the compositions in order to bring the pH of the combined compositions from about 7.0 to about 9.5 (col. 4, lines 3-10). The references differ from the instant claims insofar as they do not disclose the pH adjusting agents are alkali metal carbonates and hydroxides.

Burke et al. discloses non-irritating dentifrices and is used a general teaching to disclose agents used to adjust pH to 4.5 to 9. These include sodium hydroxide, sodium citrate, benzoate, carbonate or bicarbonate. The reference differs from the instant claims in so far as it does not disclose a two part composition wherein one part comprises a hydrogen peroxide containing compound.

It is obvious to replace one component for another equivalent component if it is recognized in the art that two components are equivalent and is not based on the Applicant disclosure. See MPEP 2144.06 II. It is also prima facie obviousness to select a known material based on its suitability for its intended use. Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have used sodium hydroxide or sodium carbonate in place of or in combination with sodium bicarbonate in the compositions of the primary reference based on the prior art's recognition that such species are equivalent in function, as supported by cited precedent.

Applicant respectfully traverses the rejection.

As noted above, the Horner et al. reference is not a proper reference. Thus, claims 56, 71 and 78 are patentable over the primary reference Williams et al.

Applicant also respectfully submits that the Winston et al. (US 4,812,308) reference has been fully addressed in previous office action responses. Besides, Winston

et al. disclose a one-component toothpaste or gel dentifrice. The disclosure includes that "sodium percarbonate cannot normally be utilized in the oral cavity because it has an excessively high pH in solution which could cause severe irritation of the gums. The presence of sodium bicarbonate in admixture therewith in a powder formulation, serves to reduce the pH and provide a safe and palatable dentifrice." See Col. 3, lines 4-10. (Emphasis added) That "a tooth powder is provided comprising a least 40% by weight of a mixture of sodium bicarbonate and sodium percarbonate which, on contact with water, rapidly releases between 0.5 to 5% active hydrogen peroxide by weight of the finished product." Tooth powders prepared in accordance with this invention provide a convenient method of supplying a premixed stable combination of sodium bicarbonate and percarbonate, in a palatable form." See Col. 2, lines 48-57. (Emphasis added) Thus, the Examiner's footnote 1 contains only half of the information disclosed by Winston et al. In addition, Winston et al. also discloses that a high amount of sodium bicarbonate is needed. Otherwise, sodium percarbonate is taught not to be usable in an oral composition. In fact, all of the references disclose this information.

Also, as admitted by the Examiner, Burke et al. (5,292,502) discloses a one-part composition, and does not disclose a two-part composition. Burke et al.'s composition is "a substantially non-irritating oral composition of acceptable taste, the dentifrice containing as the surfactant a purified sodium lauryl sulfoacetate having admixed therewith less than 18% non-dodecyl sodium sulfoacetate impurities. The purified sodium lauryl sulfoacetate, when incorporated in the oral composition in combination with a polymeric foam-enhancing nonionic material such as ethylene oxide containing polymers and oxygen-containing heterocyclic nitrogen compounds or an amphoteric compound, exhibits a further reduction in irritation potential as well as enhanced foaming properties." See Col. 1, line 61 to Col. 2, line 5. (Emphasis added) Further, it is

well recognized in the art that a one-part or component composition is not the same as a two-part or component composition.

In addition, whether one-part or two-part, Burke et al. do not supply the deficiencies of Williams et al., as noted above. Therefore, claims 56, 71 and 78 are patentable.

Claims 62, 75 and 79 are dependent from claims 56, 71 and 78, respectively, and are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (US 5,085,853) in view of Horner et al. (US 5,829,639) as applied to claims 56-58, 61, 63, 64, 67-73, 75, 76, 78, 80 and 81 in further view of Burke et al. (US 5,292,502). While Applicant does not acquiesce with the particular rejections to dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claims 56, 71, and 78. These dependent claims include all of the limitations of the base claims and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 62, 75 and 79 are also in condition for allowance for at least the same reasons as noted for claim 56, 71 and 78.

Reconsideration is respectfully requested.

3} Claims 56-57, 61-65, 67-76 and 78-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Viscio (US 5,302,375) in view of Horner et al. (US 5,829,639). Viscio discloses compositions comprising sodium percarbonate in a non-aqueous carrier. The composition may be formulated into two parts wherein the first part is a nonaqueous composition comprising a percarbonate and the second part is an aqueous composition comprising acetylsalicylic acid. The compositions comprise 40 to 70% water (col. 4, lines 60-63). The mixing of the two components will result in a mixture

have a pH of less than 10 and generally in the range of from about 8.0 to about 9.0 (col. 3, lines 60-65). The pH of the acid comprising component may be adjusted to 5.0 to about 6.5 with components such as citric acid (col. 4, lines 1-6). The pH of the acid comprising component may be adjusted to below 7.0, preferably 5.0 to 6.5 (col. 3, line 68 to col. 4, line 1). The reference also discloses using sodium hydroxide to adjust comparative compositions comprising acid to increase the pH. Gelling agents such as Carbopol 941 (Example 5) are also used in the formulations and polyethylene glycol is included as a humectant. Other components include anti-tartar agents such as tetra sodium pyrophosphate (which is also a base) and dialkali metal pyrophosphates, and peroxide stabilizers such as ethylenediaminetetraacetic acid, diethylene triaminepentaacetic acid, phosphonates such as DEQUEST (col. 6, lines 9-30). water, it rapidly releases hydrogen peroxide (col. 2, lines 48-55). Drucker, US 4,895,721 discloses tetra sodium pyrophosphate is a base that may be used to adjust pH (col. 3, lines 9-14). The reference differs from the instant claims insofar as it does not disclose the dispensers comprise a static mixer.

Horner et al. is discussed above. The reference differs from the instant claims insofar as it does not disclose the types of toothpaste or its components that may be dispensed from the dispensers. It would have been obvious to one of ordinary skill in the art to have used the dispenser comprising the static mixer to dispense the compositions of the primary reference motivated by the desire to use a dispenser that is inexpensive disposable, has at least two isolated chambers connected to a discharge nozzle so that the contents of the chambers are isolated until discharge, is reliable, comfortable to hold and easy to use and comprises a static mixer for intermixing the contents of the cylinders prior to discharge, as disclosed by the secondary reference. In regards to claims 62, 75 and 79, it would have been obvious to use sodium

hydroxide in the acid component of the compositions to ensure the compositions was at the desire pH as supported by MPEP 2144.07 (see above).

Applicant respectfully traverses the rejection.

As noted above, the Horner et al. reference is not a proper reference.

Viscio discloses a different whitening system from hydrogen peroxide. It discloses "an oral composition for whitening teeth comprising a safe and effective whitening amount of peracetic acid dissolved or suspended in a vehicle, wherein the peracetic acid is generated within the vehicle in situ by combining water, acetylsalicylic acid and a water soluble alkali metal percarbonate." See Abstract. (Emphasis added)

"One method for whitening teeth used by dental professionals involves the use of 30% hydrogen peroxide in combination with heat and light to promote the oxidation reaction. This method, although fast, is losing favor with dentists because clinical and scientific evidence shows that an effective whitening process without heat and light is desired."

See Col. 1, lines 32-39.

"Another professional method for bleaching teeth involves the use of hydrogen peroxide generating compounds such as urea peroxide (carbamide peroxide) at concentrations of 10% to achieve the desired whitening effect. Urea peroxide rapidly breaks down into hydrogen peroxide due to the water present in saliva. This method is known as an office-monitored at-home bleaching system and involves the use of a mouth guard or tray within which the bleaching agent is placed. The tray is then placed upon the teeth of the user and bleaching is allowed to take place. This method of treatment has drawbacks including tooth sensitivity, possibly due to demineralization and irritation of oral tissues.

An additional disadvantage of the tray application method is that the bleaching effect is very slow.”

See Col. 1, lines 40-54.

“There is a demand in the marketplace for a tooth whitening product that can be used at home or in private by the consumer and is safe and easy to use. A product for home use should not utilize the compositions or products for whitening teeth that are available for use by a trained dental professional. For example, the 30% hydrogen peroxide bleaching agent utilized by many dental practitioners to bleach teeth is sufficiently concentrated to be irritating and potentially dangerous for home use by the consumer.”

See col. 1, lines 55- 64.

“The present invention provides an oral composition for whitening teeth comprising a safe and effective whitening amount of peracetic acid dissolved or suspended in a vehicle, wherein the peracetic acid is generated within the vehicle in situ by combining water, acetylsalicylic acid and a water soluble alkali metal percarbonate.” (Emphasis added)

See Col. 3, lines 20-26.

In addition, and as admitted by the Examiner, Viscio does not disclose the types of toothpaste or its components that may be dispensed from the dispensers. Since there are deficiencies not supplied by the cited reference, claims 56, 71 and 78 are patentable over Viscio.

Claims 57-58, 61, 63, 64, 67-70, 72-3, 75, 76, 80 and 81 are dependent from claims 56, 71 and 78, respectively, and are also rejected under 35 U.S.C. 103(a) as being unpatentable over Viscio in view of Horner et al. (US 5,829,639). While Applicant does not acquiesce with the particular rejections to dependent claims, it is believed that these

rejections are moot in view of the remarks made in connection with independent claims 56, 71, and 78. These dependent claims include all of the limitations of the base claims and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 57-58, 61, 63, 64, 67-70, 72-3, 75, 76, 80 and 81 are also in condition for allowance.

Applicant respectfully requests that the rejection of claims 56-58, 61, 63, 64, 67-73, 75, 76, 78, 80 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Viscio (US 5,302,375) in view of Horner et al. (US 5,829,639) be withdrawn. Reconsideration is respectfully requested.

II. CONCLUSION

The applicant believes that this Amendment addresses all of the points raised in the Office Action, and requests reconsideration and allowance of the present application, with pending claims 56-58, 61-65, 67-76, and 78-81.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact the undersigned at 310-621-6415.

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Respectfully submitted,

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